

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : MICHAEL D. LAUFER, ET AL. Art Unit : Unknown  
Serial No. : Unknown Examiner : Unknown  
Filed : April 8, 2004  
Title : METHODS AND DEVICES FOR TISSUE RECONFIGURATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO-1449s.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 09/654,655, filed on September 5, 2000. The references in the attached form PTO-1449's were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: April 8, 2004

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Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 11898-002002	Application No. 09/654,655
	Applicant MICHAEL D. LAUFER, ET AL.		
	Filing Date September 5, 2000	Group Art Unit 3731	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,875,648	04-08-1975	Bone			
	AB	4,696,300	09-29-1987	Anderson			
	AC	4,705,040	11-10-1987	Mueller et al.			
	AD	4,753,469	06-28-1988	Hiscott et al.			
	AE	4,809,695	03-07-1989	Gwathmey et al.			
	AF	5,015,249	05-14-1991	Nakao et al.			
	AG	5,336,263	08-09-1994	Ersek et al.			
	AH	5,451,406	09-19-1995	Lawin et al.			
	AI	5,645,552	07-08-1997	Sherts			
	AJ	5,674,230	10-07-1997	Tovey et al.			
	AK	5,958,444	09-28-1999	Wallace et al.			
	AL	5,984,932	11-16-1999	Yoon			
	AM	6,083,202	07-04-2000	Smith			
	AN	6,086,603	07-11-2000	Termin et al.			
	AO	6,098,629	08-08-2000	Johnson et al.			
	AP	6,129,761	10-10-2000	Hubbell			
	AQ	6,152,935	11-28-2000	Kammerer et al.			
	AR	6,258,064 B1	07-10-2001	Smith et al.			
	AS	6,645,201	11-11-2003	Utley et al.			
	AT	6,660,301 B1	12-09-2003	Vogel et al.			
	AU	6,669,713 B2	12-30-2003	Adams			
	AV	2001/0049537 A1	12-06-2001	Kortenbach			
	AW	2003/0195509 A1	10-16-2003	Edwards et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AX	WO 2004/000129 A2	12-31-2002	WIPO				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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							Yes	No
	AY	WO 00/35529	06-22-2000	WIPO				
	AZ	WO 00/78229 A1	12-28-2000	WIPO				
	AAA	WO 02/094341 A2	11-28-2002	WIPO				
	ABB	WO 02/40081 A2	05-23-2002	WIPO				
	ACC	WO 02/45603 A1	06-13-2002	WIPO				
	ADD	WO 03/000115 A2	01-03-2003	WIPO				
	AEE	WO 03/004087 A1	01-16-2003	WIPO				
	AFF	WO 03/007796 A2	01-30-2003	WIPO				
	AGG	WO 03/015604 A2	02*-27-2003	WIPIO				
	AHH	WO 03/082359 A1	10-09-2003	WIPO				
	AII	WO 03/090633 A2	11-06-2003	WIPO				
	AJJ	WO 03/092498 A1	11-13-2003	WIPO				
	AKK	WO 03/092509 A1	11-13-2003	WIPO				
	ALL	WO 03/094800 A2	11-20-2003	WIPO				
	AMM	WO 03/098885 A1	11-27-2003	WIPO				
	ANN	WO 03/099137 A2	12-04-2003	WIPO				
	AOO	WO 03/099139 A1	12-04-2003	WIPO				
	APP	WO 03/099140 A1	12-04-2003	WIPO				
	AQQ	WO 03/099376 A1	12-04-2003	WIPO				
	ARR	WO 03/105917 A2	12-24-2003	WIPO				
	ASS	EP 0 975 263 B1	02-02-2000	EUROPE				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ATT	Bancewicz et al., "Yield pressure, anatomy of the cardia and gastroesophageal reflux", Journal of Surgery, 1995, Vol. 82, pp. 943-947.
	AUU	Bancewicz et al., "Yield Pressure, Anatomy of the Cervix, and Gastroesophageal Reflux", The American Journal of Gastroenterology, Vol. 91, No. 3, 1996, pp. 616-617
	AVV	Singh et al., "Evaluation of the Endoscopic Suturing System in the Treatment of GERD", Digestive Disease Week, Orange County Convention Center, pp. A-802, 314

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,387,104	05/14/02	Pugsley, Jr. et al.			
	AB						
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Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AL							
	AM							
	AN							

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,551,987	01/05/1971	J.E. Wilkinson			
	AB	5,433,721	07/18/1995	Hooven et al.			
	AC	5,465,894	11/14/1995	Clark et al.			
	AD						
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	AO							
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(37 CFR §1.98(b))			

### U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,086,600	July 11, 2000	Kortenbach			
	AB	6,352,503	March 5, 2002	Matsui et al.			
	AC						
	AD						
	AE						
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	AK						

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AL	WO 02/24080	March 28, 2002	PCT				
	AM							
	AN							
	AO							
	AP							

### Other Documents (include Author, Title, Date, and Place of Publication)

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	AS	
	AT	

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		Filing Date September 5, 2000	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,113,609	09/5/2000	Adams			
	AB						
	AC						
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	AH						
	AI						
	AJ						
	AK						

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	Applicant Michael D. Laufer, et al.		
	Filing Date March 7, 2000	Group Art Unit	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,037,433	08/16/91	Wilk, et al.			
	AB	5,222,963	06/29/93	Brinkerhoff, et al.			
	AC	5,792,153	08/11/98	Swain, et al.			
	AD	5,901,895	05/11/99	Heaton, et al.			
	AE	6,009,877	01/04/00	Edwards			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AF	EP 0 480 428 A2	04/15/92	Europe				
	AG	EP 0 576 265 A2	12/29/93	Europe				
	AH							
	AI							
	AJ							

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	AK	Boerema, M.D., "Hiatus hernia: Repair by right-sided, subhepatic, anterior gastropexy," <u>Surgery</u> , 65:884-893 (1969).
	AL	Cecconello, "Esophagogastric Anastomosis with Valvuloplasty: An Experimental Study," <u>International Surgery</u> , 67:121-124 (1982).
	AM	Collis, M.D., "Surgical Control of Reflux in Hiatus Hernia," <u>The American Journal of Surgery</u> , 115:465-471 (1968).
	AN	Collis, M.D., "An Operation for Hiatus Hernia with Short Esophagus," <u>The Journal of Thoracic Surgery</u> , 34:768-778 (1957).
	AO	Cuschieri, et al., "Multicenter prospective evaluation of laparoscopic antireflux surgery," <u>Surgical Endoscopy</u> , 7:505-510 (1993).
	AP	DeMeester, M.D. et al., "Nissen Fundoplication for Gastroesophageal Reflux Disease," <u>Annals of Surgery</u> , 204:9-20 (1986).
	AQ	Donahue, M.D., et al., "Endoscopic Control of Gastro-Esophageal Reflux: Status Report," <u>World Journal of Surgery</u> , 16:343-346 (1992).
	AR	Donahue, M.D., et al., "Endoscopic sclerosis of the gastric cardia for prevention of experimental gastroesophageal reflux," <u>Gastrointestinal Endoscopy</u> , 36:253-256 (1990).
	AS	Falk, et al., "Laparoscopic Fundoplication: A preliminary report of the technique and postoperative care," <u>Aust. N.Z. J. Surgery</u> , 62:969-972 (1992).

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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



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	Applicant Michael D. Laufer, et al.		
	Filing Date March 7, 2000	Group Art Unit	

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AT	Hill, et al., " <u>Surgerv for Peptic Esophageal Stricture</u> ," 139-147.
	AU	Hill, M.D., "An Effective Operation for Hiatal Hernia: An Eight Year Appraisal," <u>Annals of Surgerv</u> , 166:681-692 (1967).
	AV	Hill, et al., "The Esophagus. Medical and Surgicial Management," <u>WB Saunders Co.</u> , 135-8 (1988).
	AW	Hinder, et al. "The Surgical Option for Gastroesophageal Reflux Disease," Symposium on Gastroesophageal Reflux Disease. <u>Am J Med.</u> 103:144S-148S (1997).
	AX	Ismail, et al., "Yield Pressure: A New Concept in the Evaluation of Gerd?," <u>AJG</u> , 91:616-617 (1996).
	AY	Jamieson, et al., "The development of surgery for gastro-oesophageal reflux disease," <u>Surgery of the Oesophagus</u> , 233-245 (1988).
	AZ	Jamieson, et al., "Laparoscopic Nissen Fundoplication," <u>Annals of Surgerv</u> , 220:137-145 (1994).
	AAA	Janssen, et al., "Prospective randomized comparison of teres cardiopexy and Nissen fundoplication in the surgical therapy of gastro-oesophageal reflux disease," <u>Br. J.Surg.</u> 80:875-878 (1993).
	ABB	Jennings, et al., "A Novel Endoscopic Transgastric Fundoplication Procedure for Gastroesophageal Reflux: An Initial Animal Evaluation," <u>Journal of Laparoendoscopic Surgerv</u> , 2:207-213 (1992).
	ACC	Kahrilas, "Gastroesophageal Reflux Disease," <u>JAMA</u> , 276:983-988 (1996).
	ADD	Kraemer, M.D., et al., "Laparoscopic Hill repair," <u>Gastrointestinal Endoscopy</u> , 40:155-159 (1994).
	AEE	Little, M.D., "Mechanisms of Action of Antireflux Surgery: Theory and Fact," <u>World Journal of Surgerv</u> , 16:320-325 (1992).
	AFF	Mason, et al., "Nissen Fundoplication Prevents Shortening of the Sphincter During Gastric Distention," <u>ARCH SURG.</u> , 132:719-726 (1997).
	AGG	McGouran, M.D., et al., "A laser-induced scar at the cardia increases the yield pressure of the lower esophageal sphincter," <u>Gastronintestinal Endoscopy</u> , 36:439-443 (1990).
	AHH	McKernan, "Laparoscopic repair of gastroesophageal reflux disease," <u>Surgical Endoscopy</u> , 8:851-856 (1994).
	AII	Nathanson, et al., "Laparoscopic Ligamentum teres (round ligament) cardiopexy," <u>Br. J. Surg.</u> , 78:947-951 (1991).
	AJJ	Nissen, "Eine einfache Operation zur Beeinflussung der Refluxoesophagitis," <u>Journal Suisse De Medecine</u> , 590-592 (1956)
	AKK	O'Connor, et al., "Endoscopic placement of collagen at the lower esophageal sphincter to inhibit gastroesophageal reflux: a pilot study of 10 medically intractable patients," <u>Gastrointestinal Endoscopy</u> , 34:106-112 (1988).
	ALL	Pedinielli, "Traitement Chirurgical de la Herinie Hiatale Par La Technique du Collet", <u>Ann. Chir.</u> , 18:1461-1474 (1964). (English Abstract)
	AMM	Polk, et al. "Hiatal Hernia and Esophagitis: A survey of indications for operation and technic and results of fundoplication," <u>Ann. Surg.</u> , 173:775-781 (1971).
	ANN	Rampal, et al., "Technique Chirurgical, Traitement des hernies hiatales et du reflux aesophagien par la cardio-pexie avec le ligament round de foie," <u>La Presse Medicale</u> . 75:617-619 (1967).
	AOO	Rich, "Simple GERD Treatment Offers New Alternative," ( <a href="http://www.medicalpost.com">www.medicalpost.com</a> website), March 1999.

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 11898-002001	Application No. 09/520,273
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant Michael D. Laufer, et al.	
		Filing Date March 7, 2000	Group Art Unit
(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	APP	Singh, et al., "Evaluation of the Endoscopic Suturing System in the Treatment of GERD," <u>DDW</u> , May 16-19, 1999.
	AQQ	Skinner, et al., "Surgical management of esophageal reflux and hiatus hernia," <u>Journal of Thoracic and Cardiovascular Surgery</u> , 53:33-54 (1967).
	ARR	Starling, et al., "Assessment of the Angelchik Prosthesis for Treatment of Symptomatic Esophageal Reflux," <u>World J. Surg.</u> 11, 350-355 (1987).
	ASS	Tocornal, M.D., et al., "A mucosal flap valve mechanism to prevent gastroesophageal reflux and esophagitis," <u>Surgery</u> , 64:519-523 (1968).
	ATT	Wang, et al., "A new anti-flux procedure: cardiac oblique invagination," <u>Chung Hua Wai Ko Tsa Chih</u> , Feb: 33 (2) 73-5 (1995). (English Abstract)
	AUU	Watson, et al., "Comparison of anterior, posterior and total fundoplication using a viscera model," <u>Diseases of the Esophagus</u> , 10: 110-114 (1997).
	AVV	Westbrook, et al., "Posterior Surgical Approaches to the Rectum," <u>Annals of Surgery</u> , 195:677-691 (1982).

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FORM PTO-1449(Modified)	ATTY. DOCKET NO. N0388/7000	SERIAL NO. US 09/520,273
	APPLICANT Laufer et al.	
	FILING DATE 7 March 2000	GROUP unassigned

#### U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	A1	US 5,346,504	09/13/94	Ortiz et al.	606	192	
	A2	US 5,403,326	04/04/95	Harrison et al.	606	139	
	A3	US 5,558,665	09/24/96	Kieturakis	606	1	
	A4	US 5,571,116	11/05/96	Bolanos et al.	606	143	
	A5	US 5,787,897	08/04/98	Kieturakis	128	898	
	A6	US 5,810,882	09/22/98	Bolduc et al.	606	213	
	A7	US 5,887,594	03/30/99	LoCicero III et al.	128	898	

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		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No
	B1	WO 99/22649	05/14/99	PCT	A61B	17/04	

#### OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

	C1	Contractor QQ et al., Endoscopic esophagitis and gastroesophageal flap valve. <i>J Clin Gastroenterol</i> 1999 Apr;28(3):233-7.
	C2	Donahue PE et al., Endoscopic control of gastro-esophageal reflux: status report. <i>World J Surg</i> 1992 Mar-Apr;16(2):343-6.
	C3	Donahue PE et al., Endoscopic sclerosis of the gastric cardia for prevention of experimental gastroesophageal reflux. <i>Gastrointest Endosc</i> 1990 May-Jun;36(3):253-6.
	C4	Hill LD and Kozarek RA, The gastroesophageal flap valve. <i>J Clin Gastroenterol</i> 1999 Apr;28(3):194-7.
	C5	Hill LD et al., Antireflux surgery. A surgeon's look. <i>Gastroenterol Clin North Am</i> 1990 Sep;19(3):745-75.
	C6	Hill LD et al., The gastroesophageal flap valve: in vitro and in vivo observations. <i>Gastrointest Endosc</i> 1996 Nov;44(5):541-7.
	C7	Hill LD, Intraoperative measurement of lower esophageal sphincter pressure. <i>J Thorac Cardiovasc Surg</i> 1978 Mar;75(3):378-82.
	C8	Hill LD, Myths of the esophagus. <i>J Thorac Cardiovasc Surg</i> 1989 Jul;98(1):1-10.
	C9	Ismail T et al., Yield pressure, anatomy of the cardia and gastro-oesophageal reflux. <i>Br J Surg</i> 1995 Jul;82(7):943-7.



LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

APPLICANT Laufer et al.

FILING DATE 7 March 2000

GROUP 3739

## U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	A8	US 5,088,979	02/18/92	Filipi et al.	604	26	
	A9	US 5,254,126	10/19/93	Filipi et al.	606	146	
	A10	US 5,573,496	11/12/96	McPherson et al.	600	217	
	A11	US 5,676,674	10/14/97	Bolanos et al.	606	139	
	A12	US 5,897,562	04/27/99	Bolanos et al.	606	139	
	A13	US 6,067,990	08/30/00	Kieturakis	128	898	

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		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No

## OTHER ART

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	C18		Carvalho PJPC et al., Fibrosis of gastric cardia after endoscopic sclerosis. Mechanism for control of experimental reflux? <i>Am Surg</i> 1990 Mar;56(3):163-6.
	C19		Kadirkamanathan SS et al., An ambulant porcine model of acid reflux used to evaluate endoscopic gastroplasty. <i>Gut</i> 1999 Jun;44(6):782-8.
	C20		O'Connor KW et al., An experimental endoscopic technique for reversing gastroesophageal reflux in dogs by injecting inert material in the distal esophagus. <i>Gastrointest Endosc</i> 1984 Oct;30(5):275-80.
	C21		Rupp TH and Lehman GA, Endoscopic antireflux techniques. Endoluminal and laparoscopic. <i>Gastrointest Endosc Clin N Am</i> 1994 Apr;4(2):353-68.
	C22		Shafik A, Intraesophageal Polytef injection for the treatment of reflux esophagitis. <i>Surg Endosc</i> 1996 Mar;10(3):329-31.
	C23		Thor KBA et al., Reappraisal of the flap valve mechanism in the gastroesophageal junction. A study of a new valvuloplasty procedure in cadavers. <i>Acta Chir Scand</i> 1987 Jan;153(1):25-8.

\* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 11898-002002	Application No. 09/654,655
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant Michael D. Laufer, et al.	
		Filing Date September 5, 2000	Group Art Unit
(37 CFR §1.98(b))			

U.S. Patent Documents							
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	BA	5,356,416	10/18/94	Chu et al.			
	BB	5,358,508	10/25/94	Cobb			
	BC	5,364,408	11/15/94	Gordon			
	BD	5,441,507	8/15/95	Wilk			
	BE	5,447,512	9/5/95	Wilson et al.			
	BF	5,486,189	1/23/96	Mudry et al.			
	BG	5,496,331	3/5/96	Xu et al.			
	BH	5,522,820	6/4/96	Caspari et al.			
	BI	5,549,618	8/27/96	Fleenor et al.			
	BJ	5,571,090	11/5/96	Sherts			
	BK	5,624,453	4/29/97	Ahmed			
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	BZ	5,853,409	12/29/98	Swanson et al.			
	CA	5,855,311	1/5/99	Hamblin et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	CB	5,893,592	4/13/99	Schulze et al.			
	CC	5,993,466	11/30/99	Yoon			
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	CG	6,179,840	1/30/01	Bowman			
	CH	6,221,084	4/24/01	Fleenor			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	CI	00/78229	12/28/00	PCT				
	CJ							

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	CK	
	CL	
	CM	
	CN	

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